

What Is Claimed:

1. A method of diagnosing a pelvic pain disorder comprising:
measuring a level of CGRP or PACAP, or both, in a patient sample; and
5 determining if the measured level of CGRP or PACAP, or both, in the
patient sample is elevated in relation to a standard level of CGRP or PACAP in a
normal asymptomatic population, wherein the measured level of CGRP or PACAP, or
both, that is elevated relative to the standard level indicates the diagnosis of a pelvic
pain disorder.
- 10 2. The method according to claim 1, wherein said measuring
comprises use of one or both of CGRP-specific and PACAP-specific antibodies.
3. The method according to claim 1, wherein said measuring
15 comprises use of HPLC, mass spectrometry, or an assay system selected from the
group of enzyme-linked immunoabsorbent assay, radioimmunoassay, gel diffusion
precipitin reaction assay, immunodiffusion assay, agglutination assay, fluorescent
immunoassay, protein A immunoassay, and immunoelectrophoresis assay.
- 20 4. The method according to claim 1, wherein the patient sample is
a urine sample, a blood sample, or a spinal fluid sample.
5. The method according to claim 1, wherein the patient is a
mammal.
- 25 6. The method according to claim 5, wherein the mammal is a
human, cat, dog, cow, horse, pig, sheep, or rodent.
7. The method according to claim 1 further comprising:
30 correlating the measured level of CGRP or PACAP, or both, with a
range associated with the pelvic pain disorder.
8. The method according to claim 1, wherein the pelvic pain
disorder is interstitial cystitis, Crohn's disease, ulcerative colitis, irritable bowel
35 syndrome, vulvodynia, vestibulitis, endometriosis, prostatitis, orchalgia, or proctalgia.

9. A method of determining predisposition of an individual to conditions associated with pelvic pain disorders comprising:

measuring a level of CGRP or PACAP, or both, in a sample obtained from an individual; and

5 determining if the measured level of CGRP or PACAP, or both, in the sample is elevated in relation to a standard level of CGRP or PACAP in a normal asymptomatic population, wherein the measured level of CGRP or PACAP, or both, that is elevated relative to the standard level indicates the individual is predisposed to conditions associated with a pelvic pain disorder.

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10. The method according to claim 9, wherein the pelvic pain disorder is a bladder disorder and the conditions associated with the bladder disorder comprise one or more of pain during urination, urgency of urination, frequency of urination, ulcers of bladder mucosa, and petechial hemorrhages of bladder mucosa.

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11. The method according to claim 9, wherein said measuring comprises use of one or both of CGRP-specific and PACAP-specific antibodies.

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12. The method according to claim 9, wherein said measuring comprises use of HPLC, mass spectrometry, or an assay system selected from the group of enzyme-linked immunoabsorbent assay, radioimmunoassay, gel diffusion precipitin reaction assay, immunodiffusion assay, agglutination assay, fluorescent immunoassay, protein A immunoassay, and immunoelectrophoresis assay.

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13. The method according to claim 9, wherein the sample is a urine sample, a blood sample, or a spinal fluid sample.

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14. The method according to claim 9, wherein the individual is a mammal.

15. The method according to claim 15, wherein the mammal is a human, cat, dog, cow, horse, pig, sheep, or rodent.

16. The method according to claim 1 further comprising:
correlating the measured level of CGRP or PACAP level, or both, with
a range associated with pelvic pain disorders.
- 5 17. The method according to claim 9, wherein the pelvic pain
disorder is interstitial cystitis, interstitial cystitis, Crohn's disease, ulcerative colitis,
irritable bowel syndrome, vulvodynia, vestibulitis, endometriosis, prostatitis,
orchalgia, or proctalgia.
- 10 18. A method of treating a pelvic pain disorder in a patient
comprising:
providing a CGRP antagonist; and
administering the CGRP antagonist to a patient in an amount effective
to treat the pelvic pain disorder.
- 15 19. The method according to claim 18, wherein the CGRP
antagonist is BIBN4096BS.
- 20 20. The method according to claim 18, wherein the CGRP
antagonist is SB-(+)-273779 [N-methyl-N-(2-methylphenyl)-3-nitro-4-(2-
thiazolylsulfinyl)nitrobenzanilide].
21. The method according to claim 18, wherein the CGRP
antagonist is a fragment of CGRP.
- 25 22. The method according to claim 18, wherein said administering
is carried out orally, parenterally, subcutaneously, transdermally, intravenously,
intramuscularly, intraperitoneally, by intranasal instillation, by implantation, by
intracavitary or intravesical instillation, intraocularly, intraarterially, intralesionally,
30 by application to mucous membranes, or by intrabladder administration.
23. The method according to claim 18, wherein the CGRP
antagonist is present in a pharmaceutical composition comprising the CGRP
antagonist and a pharmaceutically-acceptable carrier.

24. The method according to claim 23 wherein the pharmaceutical composition is in a liquid or solid dosage form.

5 25. The method according to claim 18, wherein the patient is a mammal.

26. The method according to claim 25, wherein the mammal is a human, cat, dog, cow, horse, pig, sheep, or rodent.

10 27. The method according to claim 18, wherein said administering is effective to mitigate symptoms of the pelvic pain disorder.

15 28. The method according to claim 27, wherein the symptoms of the pelvic pain disorder comprise one or more of pain during urination, urgency of urination, frequency of urination, ulcers of bladder mucosa, and petechial hemorrhages of bladder mucosa.

20 29. The method according to claim 28, wherein the pelvic pain disorder is interstitial cystitis, interstitial cystitis, Crohn's disease, ulcerative colitis, irritable bowel syndrome, vulvodynia, vestibulitis, endometriosis, prostatitis, orchalgia, or proctalgia.

25 30. A method of characterizing response to treatment for a pelvic pain disorder comprising:
measuring a level of CGRP or PACAP, or both, in a sample obtained from a patient to be treated for a pelvic pain disorder;
treating the patient with a CGRP or PACAP antagonist; and
repeating said measuring after said treating, whereby a decrease in the CGRP or PACAP level, or both, following said treating indicates that the treatment is
30 effective.

35 31. A transgenic non-human mammal comprising a first DNA construct that is expressed in bladder sensory neurons, the first DNA construct comprising a promoter operatively coupled to a DNA molecule encoding a neuropeptide.

32. The transgenic non-human mammal according to claim 31 wherein the neuropeptide is CGRP or PACAP.

5 33. The transgenic non-human mammal according to claim 31 wherein the transgenic mammal is a human, cat, dog, cow, horse, pig, sheep, or rodent.

34. The transgenic non-human mammal according to claim 31, wherein the promoter of the first DNA construct is an inducible promoter.

10 35. The transgenic non-human mammal according to claim 34, wherein the inducible promoter comprises a tetracycline response element and is inducible in the presence of an rtTA protein and doxycycline.

15 36. The transgenic non-human mammal according to claim 35 further comprising:

a second DNA construct comprising a promoter that is specific for urothelial tissues and a DNA molecule encoding the rtTA protein.

20 37. The transgenic non-human mammal according to claim 36 further comprising:

a third DNA construct comprising an inducible promoter operably coupled to a coding sequence for peptidyl glycine α -amidating monooxygenase (PAM).

25 38. The transgenic non-human mammal according to claim 35 wherein the transgenic mammal comprises both somatic and germ cells that contain the first and second DNA constructs.

30 39. The transgenic non-human mammal according to claim 35 wherein bladder sensory neurons of the transgenic non-human mammal are infected with an infective expression vector comprising the first DNA construct.

35 40. A recombinant CGRP or PACAP polypeptide that is amidated at its carboxyl terminus.

41. The recombinant polypeptide according to claim 40, wherein the polypeptide comprises CGRP.

5 42. The recombinant polypeptide according to claim 40, wherein the polypeptide comprises PACAP.

43. A recombinant DNA construct encoding the recombinant polypeptide according to claim 40.

10 44. The recombinant DNA construct according to claim 43 comprising the nucleotide sequence of nt 905-1114 of SEQ ID NO: 1 or nt 905-1111 of SEQ ID NO: 2.

15 45. A recombinant expression vector comprising one or more recombinant DNA constructs according to claim 43.

46. A host cell transformed with the recombinant DNA construct according to claim 43.

20 47. The host cell according to claim 46, wherein the host cell is a mammalian cell.